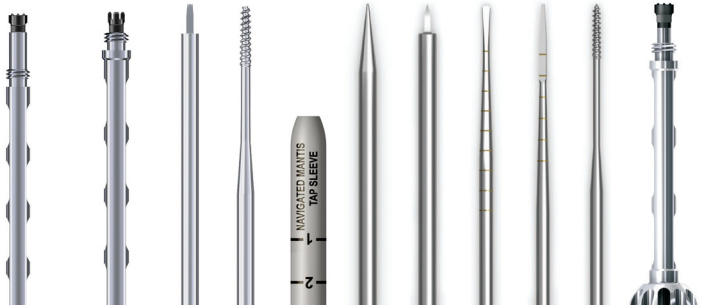
stryker®

Navigated Spine Instruments

Quick Guide

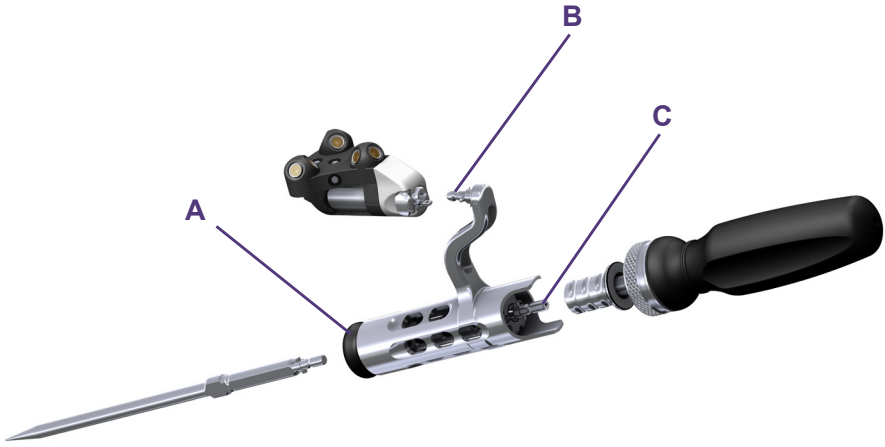


1. Introduction

The Rotational Navigation Adapter provides a connection between dedicated Spine instrument tips and a Stryker Navigation Tracker. The instrument tips can be rotated within the adapter while being tracked by the Stryker Navigation System. The Rotational Navigation Adapter provides three mechanical interfaces.

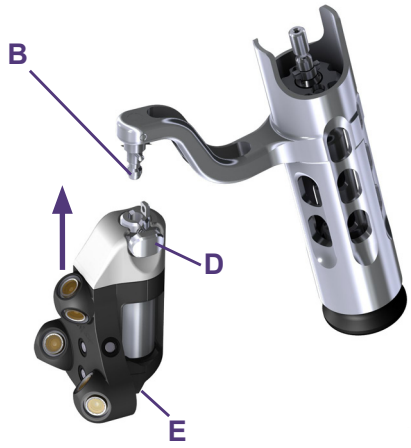
1. Navigated tip interface with coupling ring (A)
2. Navigation tracker interface (B)
3. Handle interface (C)

The Rotational Navigation Adapter shall only be used with application packages on the Stryker Navigation System which support the Rotational Navigation Adapter. The part list of the respective application provides this information.



	User Group	Medical Professional (Surgeons, scrub nurses and employees in the clinical processing department.)
	Refer to documentation	For the required safety information and contraindications, please refer to the safety informations, supplied with the software packages, to the instructions for use, supplied with the system components, tips and handles and to the surgical techniques brochures provided by Stryker Spine.
As with any technical guide, the surgeon should consider the particular condition of the patient and perform the necessary adjustments if required. Safety and caution should always be utilized before proceeding.		

2. Assemble/Disassemble instrumentation



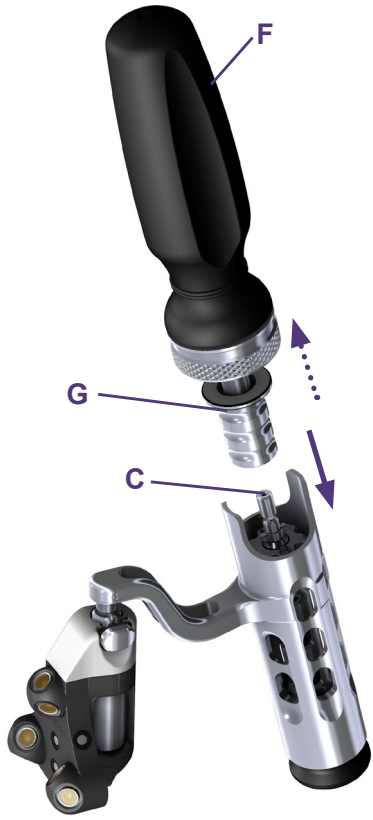
Assemble a navigation tracker

1. Press and hold the interface button (D) of the tracker interface.
2. Slide the tracker (E) on the tracker interface pin (B) of the Rotational Navigation Adapter.
3. Release the interface button (D) and move the tracker (E) slightly until the interface button snaps back and the tracker is firmly attached to the interface (B).

There are two tracker options available to interface with the Rotational Navigation Adapter:

- nGenius Universal Tracker

- Universal Tracker



Assemble a handle

1. Pull back and hold the coupling ring (G) of the handle (F).
2. Slide the handle over the handle interface (C) of the Rotational Navigation Adapter.
3. Release the coupling ring (G) of the handle (F) and turn the handle until the coupling ring snaps back into its original position and the handle is firmly attached to the interface.

There are three handle options with the Rotational Navigation Adapter. All handles are cannulated and ratcheting and can be used interchangeably with the Navigated Xia 3 and Navigated MANTIS instruments.

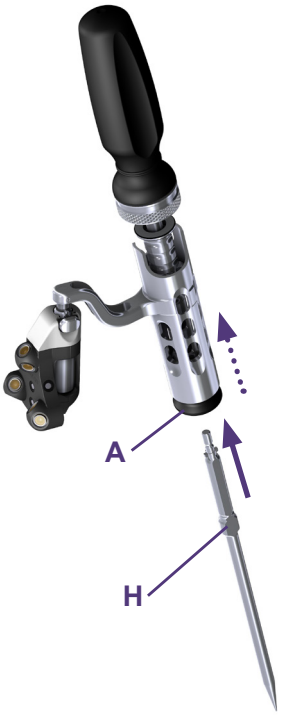
- Navigated Round Handle

- Navigated T-Handle

- Navigated T-Handle (Short)

Assemble a navigated tip

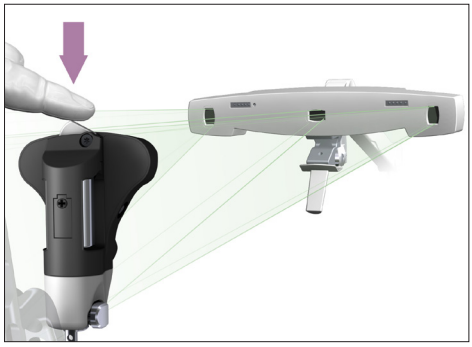
1. Pull back and hold the coupling ring (A) of the Rotational Navigation Adapter.
2. Insert the navigated tip interface (H) into the tip interface of the Rotational Navigation Adapter.
3. Release the coupling ring (A) of the Rotational Navigation Adapter and fully insert the tip until the coupling ring snaps back to its original position.
4. Check that the tip is firmly attached to the tip interface. The tip is correctly seated if the slope of the tip is aligned with the adapter interface as shown in the following:

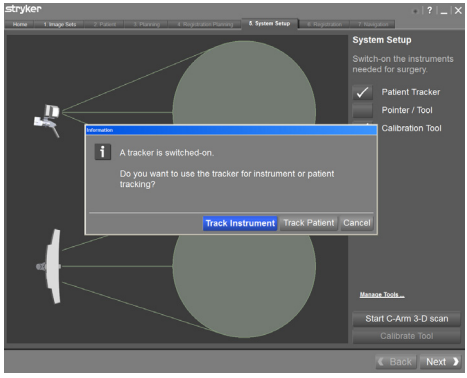


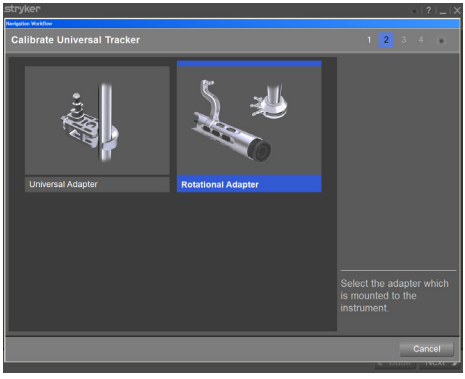
Fully inserted Polyaxial Screwdriver

Fully inserted Calibration Tip

3. Calibrate Rotational Navigation Adapter







Prepare tools

1. For adapter calibration (Navigated Xia 3 and Navigated MANTIS) the navigated Calibration Tip must be used.
2. Attach a tracker, a handle and the Calibration Tip onto the Rotational Navigation Adapter. Check that the Calibration Tip is firmly attached to the tip interface.
3. Initialize the tracker by pressing **SELECT** for three seconds. Upon initialization, an information box appears.
4. Highlight and select **Track Instrument**. An instrument calibration dialog starts.

Initialize calibration device

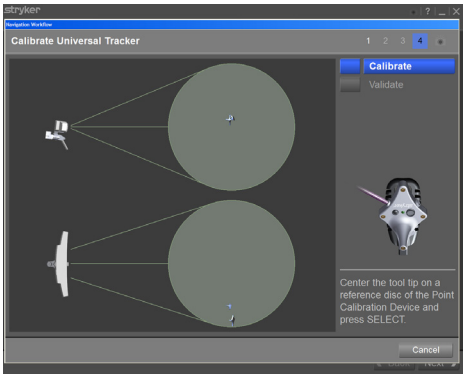
- Initialize the Point Calibration Device (PCD) by pressing **SELECT** for three seconds. Upon initialization, an information box appears.

Select adapter

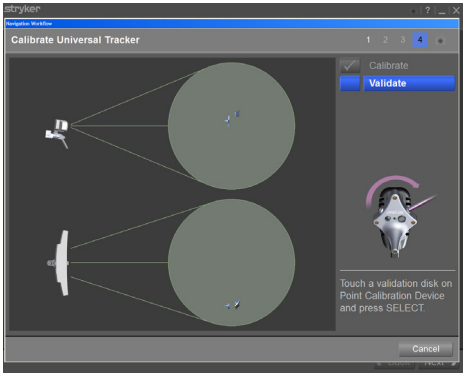
- Highlight and select **Rotational Adapter** by pressing **SELECT** on the PCD.

Calibrate Rotational Adapter

1. Make sure that both the PCD and the tool tracker are visible and centered in the working space of the camera.
2. Touch the center of any of the PCD's validation discs with the tip of the Calibration Tip and press **SELECT** on the PCD to confirm.
3. Touch the center of the validation disc on the opposite side of the PCD with the tip of the calibration instrument and press **SELECT** on the PCD to confirm.

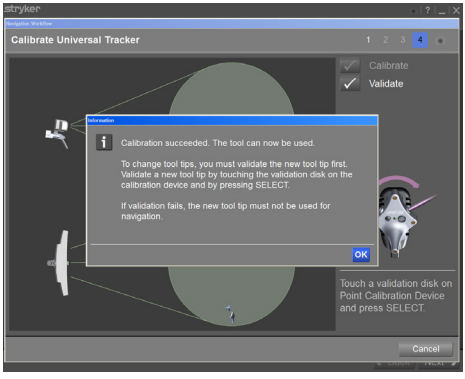


- After the calibration, the Calibration Tip can be removed and replaced by one of the navigated Spine instrument tips. The tips must be validated according to the next step.



Validate Rotational Adapter calibration

1. Insert the required tip into the tip interface of the Rotational Navigation Adapter and check that the tip is firmly attached to the tip interface.
2. Make sure that both the PCD and the tool tracker are visible and centered in the working space of the camera.
3. Touch the center of any of the PCD's validation discs with the tip of the navigated Spine Instrument and press **SELECT** on the PCD to confirm.


stryker
Calibrate Universal Tracker
1 2 3 4
Calibrate
Validate
Information
Calibration succeeded. The tool can now be used.
To change tool tips, you must validate the new tool tip first. Validate a new tool tip by touching the validation disk on the calibration device and by pressing SELECT.
If validation fails, the new tool tip must not be used for navigation.
OK
Touch a validation disk on Point Calibration Device and press SELECT.
Cancel

- If you change tools, validate the new tool before usage.

1. Use of Navigated Xia 3 Instrument Tips

The Navigated Xia 3 Instrument Tips are designed to be used with the Stryker Xia 3 Spinal System. The Navigated Xia 3 Instrument Tips include:

- Awl
- Straight Blunt Probe
- Straight Thoracic Pedicle Probe
- Modular Taps
- Polyaxial Screwdriver

The Navigated Xia 3 Instrument Tips are assembled to the Rotational Navigation Adapter using the methodology described in the chapters before.

The Polyaxial Screwdriver has a marking on the long, round shaped sides of the interface. This marking indicates the correct seating of the Polyaxial Screwdriver when it meets the adapter interface.

2. Prepare Pedicles

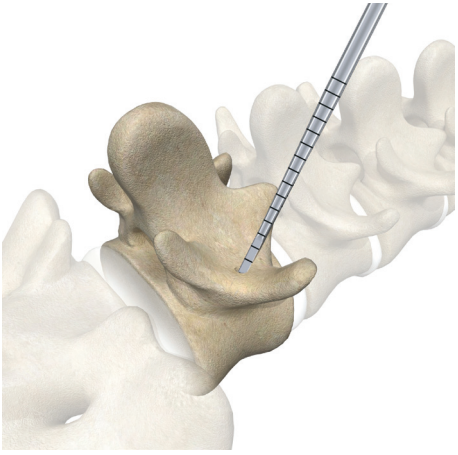
Prepare the entry point with the Awl. The Awl is designed with a stop at 13 mm to prevent overplunging.

Use the Straight Blunt Probe or the Straight Thoracic Pedicle Probe to create a pathway into the pedicle.

The navigated insertion of the instrument allows the probe tip to follow a path of least resistance without violating the pedicle walls. In the case that resistance is met, the entry point and trajectory should be reevaluated.

The Straight Blunt Probe and the Straight Thoracic Pedicle Probe are laser marked in 10 mm intervals to help indicate the depth in which the probe tip has been inserted.

Next to the navigational infomation, these depth indicators on the probe tips are also helpful in determining the appropriate pedicle screw length.



Probes

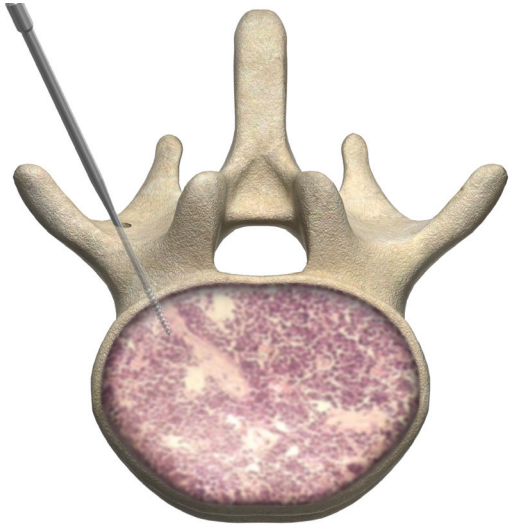
There are two probe options available. The primary differentiating feature of the Straight Blunt Probe and the Straight Thoracic Pedicle Probe is the distal end. The Straight Blunt Probe has a flat distal end whereas the Straight Thoracic Pedicle Probe has a sharp, pointy distal end designed to optimize its use in the thoracic region of the spine.

Straight Blunt Probe

Straight Thoracic Pedicle Probe

Modular Taps

For increased bone purchase, use the Modular Taps to prepare the pedicle canal. Insert the Modular Tap into the pedicle and into the vertebral body. The Modular Taps are laser marked with lines in 5 mm increments and numbers in 10 mm increments.



3. Insert Screws

With the pedicle pathway prepared, and the proper screw diameter and length determined using the SpineMap 3D software, the screw can be inserted into the pedicle using the Navigated Xia 3 Polyaxial Screwdriver.

Navigated Xia 3 Polyaxial Screwdriver

The Navigated Xia 3 Polyaxial Screwdriver includes a locking feature that is designed to provide tactile, visual, and audible confirmation that the Polyaxial Screwdriver is securely locked.

To engage the Navigated Xia 3 Polyaxial Screwdriver:

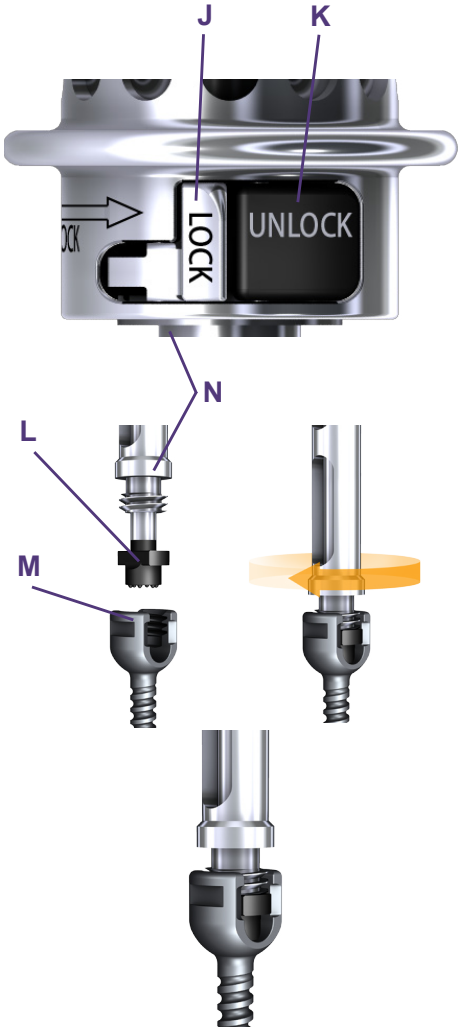
1. Press the **UNLOCK** button (K).
2. Hold the screw by the threads and engage the tabs on the screwdriver tip (L) into the saddle of the screw head (M).
3. Fully seat the screwdriver tip (L) into the screw head (M).
4. Turn the outer shaft (N) clockwise using the **LOCK** button (J) until the threads are fully engaged.

- If the ratchet sound is not present, confirm locking by pressing the **LOCK** button (J).
- **LOCK** button can be pressed at any time during or after the thread engagement action, if ratchet sound is not desired.

To disengage the Navigated Xia 3 Polyaxial Screwdriver:

1. Press and release the **UNLOCK** button (K).
2. Rotate the outer shaft (N) counterclockwise while firmly holding the handle.

Once all of the screws have been placed; refer to the Xia 3 Spinal System Surgical Technique for rod contouring, rod linkage, final tightening, and cross connector placement.



1. Use of Navigated MANTIS Instrumentation

The Navigated MANTIS Instruments are designed to be used with the Stryker MANTIS Spinal System. The Navigated MANTIS Instruments include:

- Cannulated Awl
- Cannulated Taps
- MANTIS Polyaxial Screwdriver
- Reduction Polyaxial Screwdriver
- Tap Sleeve

The Navigated MANTIS Instrument Tips are assembled to the Rotational Navigation Adapter using the methodology described in the chapters before.

The MANTIS and MANTIS Reduction Polyaxial Screwdrivers have a marking on the long, round shaped sides of the interface. This marking indicates the correct seating of the Polyaxial Screwdrivers when they meet the adapter interface.

2. Access Pedicles

Incision

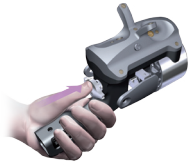
- Refer to MANTIS or MANTIS Redux Surgical Technique.

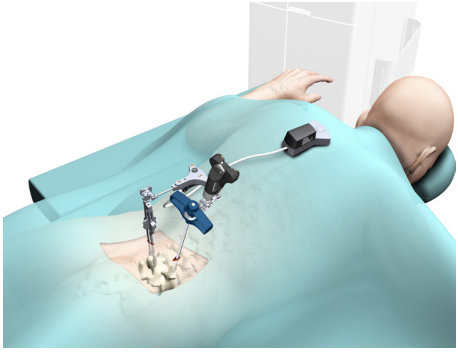
Calibrate Navigated Instrument

- Refer to Rotational Navigation Adapter Chapter in this document.

Vector Calibrate Navigated Jam Shidi

- Refer to SpineMap 3D User Manual.





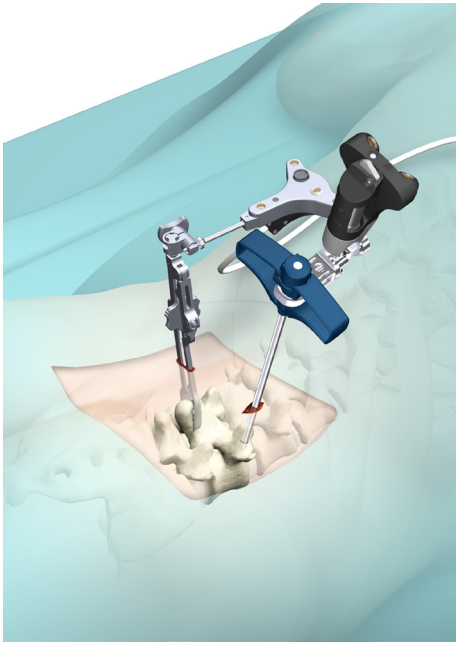
Insert K-Wire

- Insert the Navigated Jam Shidi through the skin incision to the intersection of the facet and transverse process.
- Confirm that the appropriate pedicle starting place has been determined using Navigation.

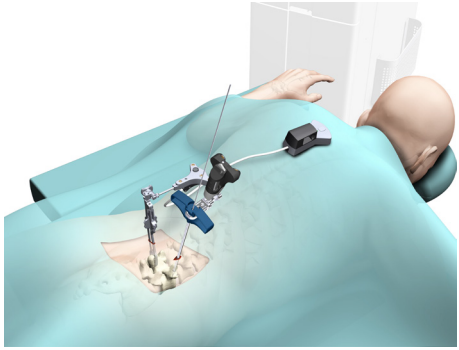
The diameter of the MANTIS K-Wire is 1.3 mm.

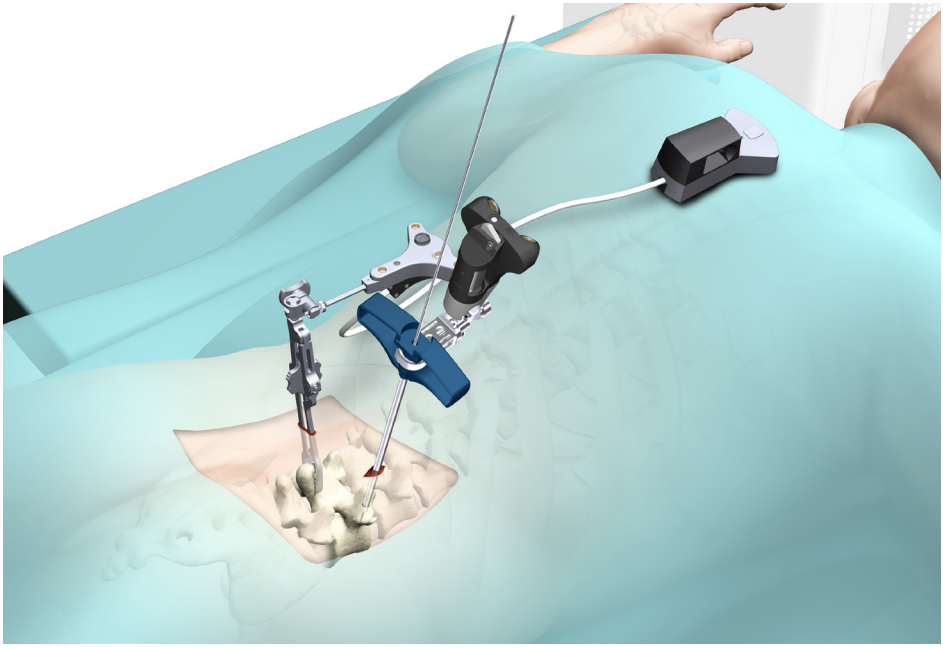
The Radius K-Wire is not compatible with the MANTIS Spinal System.

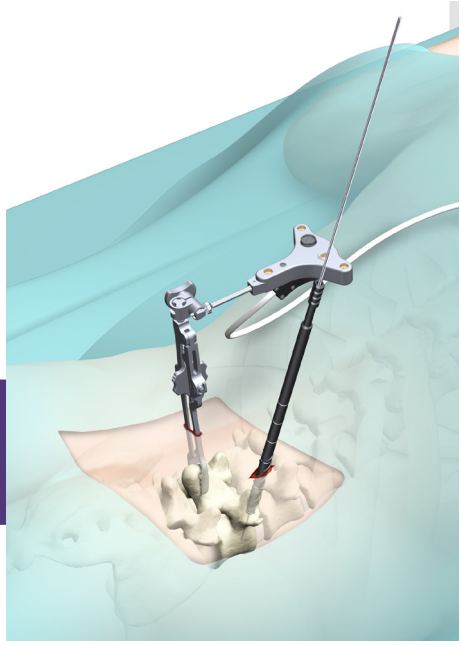
- Use the Navigated Jam Shidi needle to gain access to the pedicle.
- After placing the Navigated Jam Shidi at the intersection of the facet and the transverse process, the needle may be advanced partially through the pedicle using the Slap Hammer.
- Remove the inner trocar of the Navigated Jam Shidi.
- The removal of the Navigated Jam Shidi inner trocar allows the K-Wire to be inserted into the pedicle.
- Caution should be practiced with regard to the position of the K-Wire in order to avoid the advancement of the K-Wire.
- Insert the K-Wire - impact to the desired depth using the Slap Hammer.
- The K-Wire Guide Tube can also be utilized to aid in K-Wire Insertion.



- Once the K-Wire is inserted, remove the outer shaft of the Navigated Jam Shidi.
- Hold the K-Wire in position when removing the Navigated Jam Shidi.







Dilation

- Insert the Slim Dilator through the incision and over the K-Wire.
- Advance the Slim Dilator, through the tissue twisting clockwise while directing it toward the pedicle.
- The Slim Dilator is advanced through the lumbodorsal fascia and docked on the junction of the facet and the transverse process.
- Confirm the location of the Slim Dilator using imaging.
- Note the depth marking of the Slim Dilator in relation to the skin.

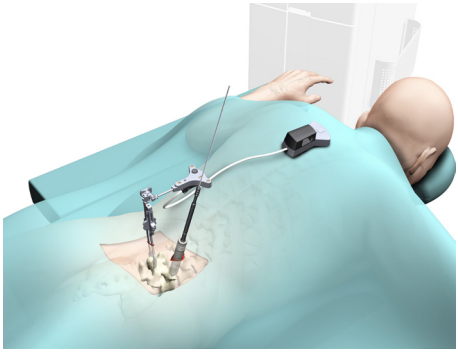
The dilators have depth markings laser etched which correlate to the blade lengths.

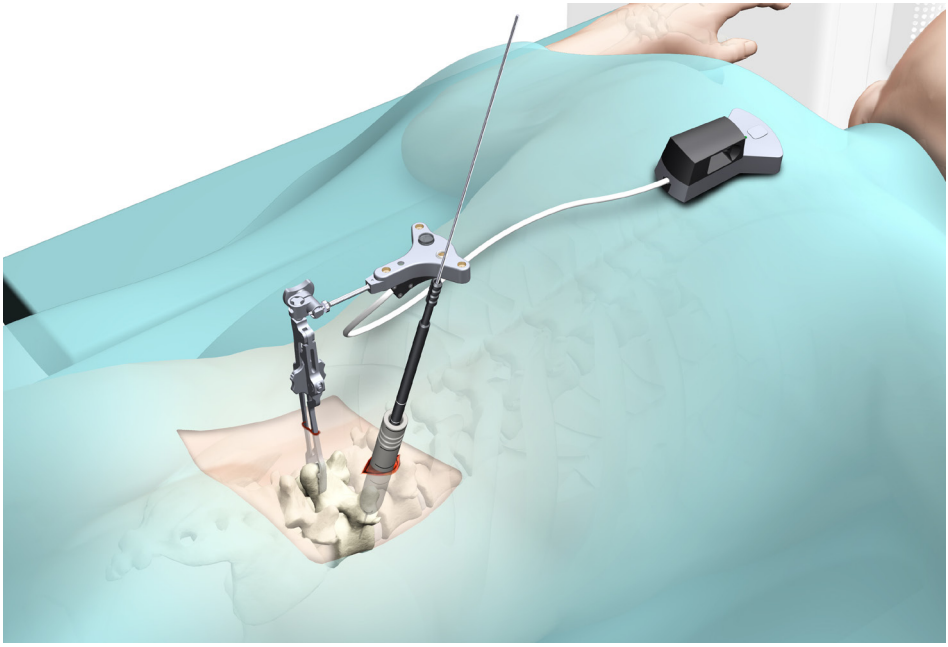
- Choose a Blade or Redux Blade length based on where the top of the skin meets the Slim Dilator.

The markings on the dilators are intended to be a guide. If it is desired to have a longer blade extend for manipulation purposes, you may select a blade one level higher than the measurement on the skin

- Slide the Navigated MANTIS Tap Sleeve over the Slim Dilator.
- Remove the Slim Dilator, making sure to leave the Navigated MANTIS Tap Sleeve in place.
- The Navigated MANTIS Tap Sleeve will be the working channel during pedicle preparation.

MANTIS Dilators can be used to dilate tissue if desired, but must be removed before using Navigated Instrumentation because the MANTIS Hollow Dilator is too long to be used with Navigated MANTIS Instrumentation. The MANTIS Hollow Dilator was designed to be used with MANTIS Blades up to Size 5, and would prevent use of the Navigated MANTIS Instruments (which were designed to be used with blades up to Size 4)





3. Prepare Pedicles

Awl

- With the Navigated MANTIS Tap Sleeve still in place, prepare the pedicle by placing the Cannulated Awl over the K-Wire and impact into the pedicle with a twisting motion.
- Use the cannulation of the Slap Hammer to impact the Awl.
- Hold the K-Wire in position when removing the Awl.

The Awl has a stop at 13.0 mm.

Monitor the position of the K-Wire to ensure that it is not advanced while awling.

Tap

- The appropriate Cannulated Tap may be used to prepare the pedicle screw canal.
- The Cannulated Taps are designed to be used with the Navigated MANTIS Tap Sleeve and laser etched with 5.0 mm intervals to help indicate the depth at which the Tap has been inserted as well as to help determine proper screw length.

The length of the Tap thread is 25 mm.

- As an instrument advances into the pedicle, the proximal end of the instrument will move relative to the markings on the K-Wire. If this does not occur during insertion the procedure should be stopped and fluoroscopy should be used to verify the position of the K-Wire in relation to the Awl or Tap.

The 1.0 cm interval markings on the K-Wire provide the cannulated instruments change in depth in the pedicle.

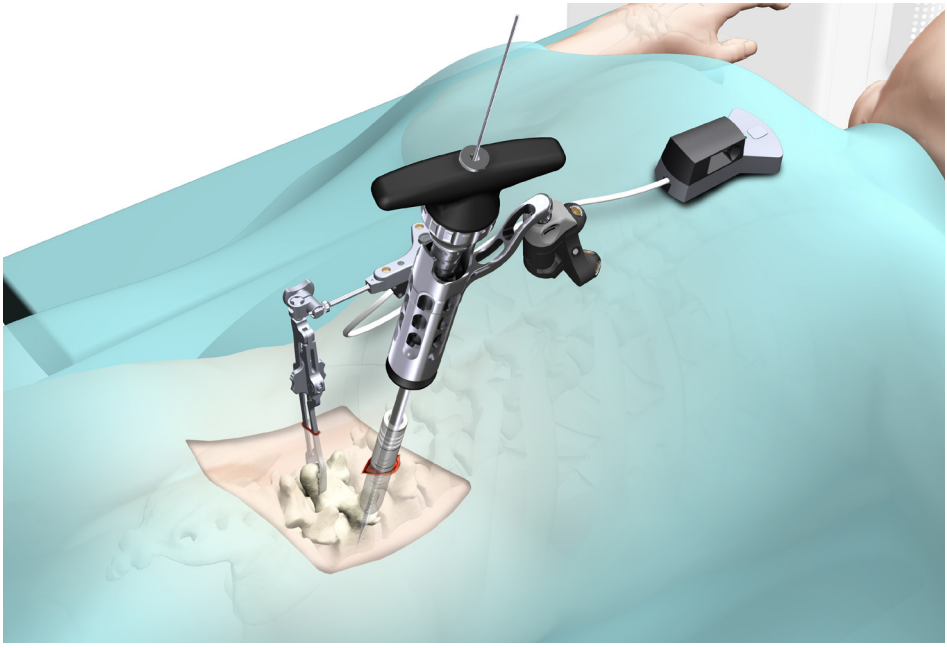
Cantilevering the Awl and Taps while in the pedicle may damage the instrument.

Monitor the position of the K-Wire to ensure that it is not advanced while tapping

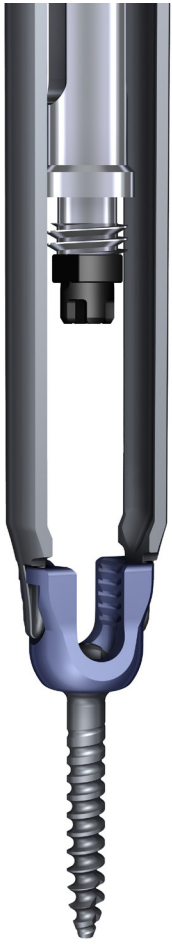
- Check pedicle depth with either Navigation or read the depth from the Navigated MANTIS Tap Sleeve as it moves along the proximal edge of the sleeve. There are markings at 30, 40 and 50 mm.

The Navigated MANTIS Tap Sleeve is made of radiolucent material.

- Hold the K-Wire in position when removing the Cannulated Tap.



4. Assemble/Insert Screws



Assemble Screw

- Refer to MANTIS or MANTIS Redux Surgical Technique.

Insert Screw

- With the pedicle pathway prepared, the proper screw diameter and length determined using the SpineMap 3D software, and the screw assembled, the screw can be inserted into the pedicle using the Navigated MANTIS Polyaxial or Polyaxial Reduction Screwdriver.

Monitor the position of the K-Wire to ensure that it is not advanced during screw insertion.

Whenever a K-Wire is being used during screw insertion, the Short T-Handle should be used with the Cannulated Awl and Cannulated Tap. When using a Round Handle or T-Handle, the K-Wire length may not be sufficient to pass through the entire instrument assembly.

- The Navigated MANTIS Polyaxial and Polyaxial Reduction Screwdrivers include a locking feature that is designed to provide tactile, visual, and audible confirmation that the Polyaxial Screwdriver is securely locked.

To engage the Navigated MANTIS Polyaxial or Polyaxial Reduction Screwdriver:

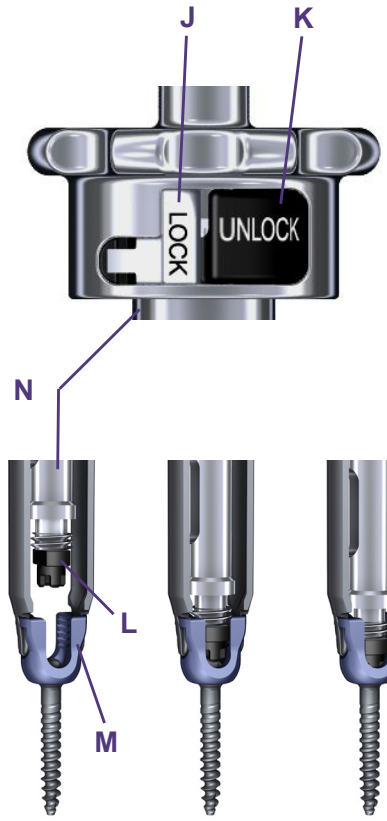
1. Press the **UNLOCK** button (K).
2. Hold the screw by the threads and engage the tabs on the screwdriver tip (L) into the saddle of the screw head (M).
3. Fully seat the screwdriver tip (L) into the screw head (M).
4. Turn the outer shaft (N) clockwise using the **LOCK** button (J) until the threads are fully engaged.

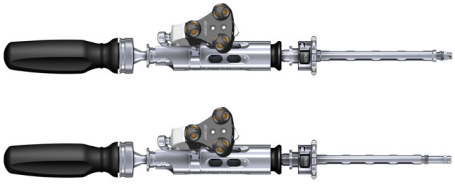
- If the ratchet sound is not present, confirm locking by pressing the **LOCK** button (J).
- **LOCK** button can be pressed at any time during or after the thread engagement action, if ratchet sound is not desired.

To disengage the Navigated MANTIS Polyaxial and Polyaxial Reduction Screwdriver:

1. Press and release the **UNLOCK** button (K).
2. Rotate the outer shaft (N) counterclockwise while firmly holding the handle.

Once all of the screws have been placed; refer to the MANTIS or MANTIS Redux Surgical Technique for the remainder of the procedure.





Part List

		Rotational Navigation Adapter
	6002-050-000	Rotational Navigation Adapter
		Tracker
	6000-014-000	nGenius Universal Tracker
	6000-005-000	Universal Tracker
		Calibration Tip
	48761020	Navigated Xia 3 Calibration Tip
		Xia 3 Awl
	48761111	Navigated Xia 3 Awl
		MANTIS Awl
	48765111	Navigated MANTIS Cannulated Awl
		Xia 3 Probes
	48761155	Navigated Xia 3 Thoracic Pedicle Probe
	48761062	Navigated Xia 3 Blunt Probe
		Xia 3 Taps
	48761040	Navigated Xia 3 Tap 4.0 mm
	48761045	Navigated Xia 3 Tap 4.5 mm
	48761050	Navigated Xia 3 Tap 5.0 mm
	48761055	Navigated Xia 3 Tap 5.5 mm
	48761065	Navigated Xia 3 Tap 6.5 mm
	48761075	Navigated Xia 3 Tap 7.5 mm

		MANTIS Taps
	48765045	Navigated MANTIS Cannulated Tap 4.5 mm
	48765055	Navigated MANTIS Cannulated Tap 5.5 mm
	48765065	Navigated MANTIS Cannulated Tap 6.5 mm
	48765075	Navigated MANTIS Cannulated Tap 7.5 mm
	48765085	Navigated MANTIS Cannulated Tap 8.5 mm
	48765300	Navigated MANTIS Tap Sleeve
		Xia 3 Screwdriver
	48761330	Navigated Xia 3 Polyaxial Screwdriver
		MANTIS/REDUX Screwdrivers
	48765310	Navigated MANTIS Polyaxial Screwdriver
	48765330	Navigated MANTIS Reduction Polyaxial Screwdriver
		Handles
	48769300	Navigated Xia 3 Round Handle, Ratchet, Cannulated
	48769200	Navigated XIA 3 T-Handle, Ratchet, Cannulated
	48769210	Navigated MANTIS Short T-Handle, Ratchet, Cannulated
		Xia 3 Tray
	48761001	Navigated XIA 3 Tray
		MANTIS Tray
	48765001	Navigated MANTIS Tray

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